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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
O,K	#9
ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 07/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/849,543

Applicant(s)
Cham

Examiner
O

Group Art Unit
3735



☒ Responsive to communication(s) filed on May 26, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-22 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) 5-7 is/are allowed.

☒ Claim(s) 1-4 and 8-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 3308

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cham (4,895,558).

In regards to claim 1 and 2:

Applicant claims a method for removal of cholesterol, triglycerides and other lipids from plasma and serum comprising withdrawing blood, separating the blood, and mixing with a solvent which extracts lipids after which the blood is returned to the subject. Such lipid apheresis or LDL apheresis is known in the art. Cham discloses the method of LDL apheresis comprising drawing blood, separating the plasma, delipidating the plasma with a lipid solvent and remixing the dilipidated with the red blood cell for re-introduction to the body. The extraction solvent in Cham is substantially removed by washing with a second solvent (ether).

In regards to Claim 15-22:

Such characteristics are inherent.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham (4,895,558) in view of Rauh et al (5,401,415).

In regards to Claims 8-11, 13, and 14:

Cham does not disclose the use of an absorbent specific for the extraction solvent. However, Rauh discloses the use of "glass beads" to extract the solvated lipids which are considered to be Applicant's "sintered spheres". Furthermore, it is stated in Rauh the use for the adsorption methods in apheresis systems (col. 1, lines 47-64). The beads provide the physical filtration system for the lipids which does not require the separation of two aqueous components. It would have been obvious to one of ordinary skill in the art to put glass bead for extraction of lipids in the Cham device to facilitate the process of filtration without the need to separate two aqueous components. Rauh's sintered spheres are considered to have the characteristics of features as claimed in Claims 9-11, 13, 14

In regards to Claim 12:

Cham does not disclose the dilipidated fraction to pass through the absorbent at least twice as claimed in Claim 12. However, such method is obvious. The Applicant undoubtedly provides multiplied effects when absorbent method is used twice, but it is not the type of innovation for which a patent monopoly is to be granted. It is difficult to conceive of a more obvious method of multiplying the effect than by passing it through twice.

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5. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham (4,895,558).

In regards to Claim 3:

Cham does not disclose washing the solvent 4 times as claimed in Claim 3. However, such method is obvious. The Applicant undoubtedly provides multiplied effects when washing multiple times, but it is not the type of innovation for which a patent monopoly is to be granted. It is difficult to conceive of a more obvious method of multiplying the effect than by washing it more than once.

In regards to Claim 4:

Cham does not disclose the use of the use of solvent diethyl ether as claimed in Claim 4, but rather di-isopropylether (DIPE). The polar characteristics of the solvents are very similar and the applicant does not disclose the criticality for the use of diethyl ether. Therefore, it would have been obvious matter of design choice to employ such use of diethethyl ether on the Cham device since the applicant has not disclosed that such solves any stated problem or is for any particular purpose, and it appears the method would work equally well with various other solvents.

Allowable Subject Matter

6. Claims 5-7 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter:

The use of the beads which has a density substantially mid-way between the density of the fraction and the density of the solvent with the other claimed methods is patentably distinct and it

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appears that no other prior art teach of such use of beads. It is considered critical to isolate the fractions.

Response to Amendment

The Applicant's Amendment has been received and entered. Currently, Claims 1-22 are still pending. The Examiner will address Applicant's remarks and arguments.

In light of Applicant remarks concerning the IDS, the German patent document DE 33 10 263 AI has been considered.

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Applicant makes a distinction between LDL apheresis and lipid apheresis as being the reason why the prior art of record does not apply to Applicant's methods. Applicant states that the proteins as well as the lipids are removed in LDL apheresis. Applicant claims a lipid apheresis and not an LDL apheresis. Examiner agrees that LDL apheresis is known to include the protein removal as well as the lipid removal which is more limiting than the lipid apheresis, however, Examiner makes that distinction moot in the rejection. Applicant claims the methods of withdrawing blood from a subject, fractionating the blood, separating the fraction from the blood, and returning the blood. These are all elements disclosed by Cham (4,895,558). In fact, the lipid apheresis disclosed by Applicant is considered a more broad claim than Cham. Cham discloses removal of lipids and proteins. Applicant discloses removal of lipids, but that does not mean that Cham's invention does not read on Applicant's claims. LDL apheresis is considered a narrow form of lipid apheresis and therefore a claim subject to lipid apheresis inherently discloses the reading of LDL apheresis.

The term "discontinuous" does not make all the claimed limitations as specified by the Applicant, i.e. in no way does "discontinuous" considered in the art to specifically meant carrying out the solvent extraction step separately and remotely from the subject. Cham is considered to disclose a discontinuous system.

Applicant's other arguments are not found persuasive. Therefore, the rejection is not removed.

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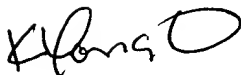
Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ki O whose telephone number is (703) 308-2681.



Ki Yong O

July 20, 1998



Aaron J. Lewis
Primary Examiner